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United States General Accounting Office

GAO

Fact Sheet for the Honorable
Frank Horton, House of Representatives

August 1986

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FDA's Investigation of Imported Apple Juice Concentrate

GAO/RCED-86-214FS

GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-223906

August 29, 1986

The Honorable Frank Horton
House of Representatives

Dear Mr. Horton:

In your June 3, 1985, letter, you requested that we review the Food and Drug Administration's (FDA's) efforts to protect the public from exposure to illegal pesticide residues on foodstuffs imported into the United States. As part of the overall review, you asked us to separately review two concerns: (1) federal agency actions in dealing with the contamination of imported wines with the industrial chemical diethylene glycol and (2) FDA's fiscal year 1985 investigation on imported apple juice concentrate. On November 20, 1985, we agreed with your staff that we would first provide you with a report on the imported wines. That report, Imported Wines: Identifying and Removing Wines Contaminated With Diethylene Glycol (GAO/RCED-86-112), was issued March 4, 1986, and was followed by testimony before the Subcommittee on Commerce, Consumer, and Monetary Affairs, House Committee on Government Operations, on May 28, 1986. On June 18, 1986, we briefed your staff on the preliminary results of our work on imported apple juice concentrate and agreed to provide a written document on the results of our work.

This fact sheet provides information on the volume of imported apple juice concentrate, FDA's testing methodology, and FDA's testing results of its special investigation on imported apple juice concentrate. On March 6, 1985, FDA began its special investigation on imported apple juice concentrate. All FDA district offices were instructed to sample each shipment of imported apple juice concentrate through May 8, 1985. In summary, 16 FDA districts collected a total of 267 samples, representing imports from 18 countries. Each sample was analyzed for those chemical residues that FDA would usually test. In addition, each sample was tested for mercury and daminozide because of allegations that levels of these chemicals, not usually tested for, were present in imported apple juice concentrate. FDA's sampling and testing results indicate that most samples contained no detectable residues. In those samples in which residues were detected, the levels were well below allowable levels. FDA officials concluded that these results provide continuing assurance of the safety of imported apple juice and apple juice concentrate.

In addition, as requested by your office, we have included information concerning the reasons why FDA added distilled water to the apple juice concentrate before testing it rather than testing it in its imported form. The major reason for adding distilled water was that all samples would, therefore, be tested on a consistent basis and in the manner they are normally consumed--that is, as single-strength juice. FDA tested imported apple juice concentrates in the same manner that it tests domestic apple juice concentrates--as single-strength juice.

We obtained information primarily at FDA's Center for Food Safety and Applied Nutrition in Washington, D.C. We also contacted the Office of Pesticides and Toxic Substances at the Environmental Protection Agency; the New York Farm Bureau; and the American Farm Bureau Federation headquarters in Washington, D.C.

Section 1 of this fact sheet provides background information on apple juice concentrate. Section 2 describes our objectives, scope, and methodology. Sections 3 and 4 provide detailed information on the methodology and results of the FDA special investigation.

We discussed the contents of this fact sheet with FDA officials and have incorporated their comments where appropriate. As discussed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this fact sheet until 30 days after its issue date. At that time we will send copies to the Commissioner of FDA and other interested parties and will make copies available to others upon request. If you have any further questions on these matters, please contact me at (202) 275-5489.

Sincerely yours,

Hugh J. Wessinger

Hugh J. Wessinger
Senior Associate Director

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ABBREVIATIONS

FDA	Food and Drug Administration
GAO	General Accounting Office
ppm	parts per million

SECTION 1

BACKGROUND

Apple juice has been one of the most popular and fastest-growing beverages in the United States during the last 20 years. The growth of the apple juice market began around 1970. Total apple juice sales grew from an equivalent usage of about 18 million bushels of apples in the late 1960's to over 90 million bushels during crop year 1983-84--or about a fivefold growth during this period. However, since the late 1970's, most of the growth in apple juice consumption by U.S. consumers has been met by imports of concentrated apple juice. Currently, imported apple juice concentrate accounts for more than half of all apple juice consumed in the United States.

APPLE JUICE CONCENTRATE

Apple juice concentrate comprises virtually all of the volume of apple juice imports entering the United States. Concentrate is produced from juice pressed from apples. Concentration is an energy-intensive process which removes water from the juice by a method called "flash evaporation." This concentration method increases the relative apple solids and sugar content (the "brix" level) of the juice by reducing the water content. Depending on the combination of time and temperature to which the juice is exposed, concentrate of various brix levels may be produced. The most common brix level is called "six-strength concentrate"--that is, it is six times more concentrated than single-strength juice (or the juice originally produced from pressing the apples). Unlike other concentrate levels, six-strength concentrate does not require refrigeration.

Virtually all imported apple juice enters the United States as six-strength concentrate. Concentrate is reconstituted to produce processed retail juice products labeled on retail shelves as "made from concentrate."

INCREASED IMPORTS

Imports of apple juice concentrate have expanded dramatically in recent years. Between 1980 and 1985, the volume of imported apple juice and juice concentrate increased fivefold.

Specific import data on apple juice concentrate are not available. However, the U.S. Department of Commerce, Bureau of Census, does compile and publish U.S. import statistics for products categorized as "apple or pear juice." According to Food and Drug Administration (FDA) officials and the American Farm Bureau Federation, six-strength apple juice concentrate comprises about 95 percent of the volume of this import category. On the basis of this information, table 1.1 shows the approximate equivalent volume of single-strength apple juice derived from imported apple juice concentrate.

Table 1.1: Estimate of Equivalent Volume of Single-Strength Apple Juice Imported in Concentrated Form Between Calendar Years 1980-85

Year	Gallons (millions)
1980	41.3
1981	77.5
1982	98.5
1983	141.8
1984	159.5
1985	203.7

Source: GAO calculations based on Bureau of Census, FDA, and American Farm Bureau Federation estimates.

The market share of U.S. apple juice supplied by imported apple juice concentrate has also risen in the past 5 years. The share of the U.S. apple juice market taken by imports increased from 19.3 percent in crop year 1980-81 to an estimated 53.7 percent in crop year 1984-85. Thus, imported apple juice concentrate now accounts for more than half of all apple juice consumed in the United States, even though the United States has the second largest apple crop in the world.

THE FDA PESTICIDE MONITORING PROGRAM

The variety and usage of pesticides have increased both in the United States and worldwide in recent decades. Public interest and concern also have grown about risks to health from pesticide residues on the U.S. food supply. To address these concerns, FDA conducts a program to monitor foods for pesticide residues. FDA collects and analyzes about 12,000 commodity samples yearly; approximately 60 percent are domestic and 40 percent are imported. Two companion reports that we are developing will describe the role of FDA in pesticide regulation and the coverage of FDA monitoring for pesticide residues in domestic and imported foods. The broad issues of sampling, testing, and enforcement will be addressed in these two reports.

Imported apple juice and apple juice concentrate are subject to testing under this FDA program. According to FDA monitoring data, four samples were tested in fiscal year 1983; 9 samples were tested in fiscal year 1984; and 276 samples were tested in fiscal year 1985 (267 samples were part of the special investigation). FDA also samples and tests domestic apple juice, concentrate or cider: 6 samples were tested in fiscal year 1983; 12 samples in fiscal year 1984; and 21 samples in fiscal year 1985. No illegal pesticide levels were found in the imported or domestic samples tested during fiscal year 1983 through fiscal year 1985.

FDA issued an Import Alert in September 1983 concerning apple juice from Argentina. This Import Alert was issued in response to reports from trade associations that private laboratory testing of apple juice from Argentina revealed pesticide residues and evidence of rotten apples in the juice. FDA monitoring tests of seven samples of apple juice concentrate from Argentina between September 1983 and July 1984 showed that none of the samples contained illegal levels of pesticide residues. In addition, FDA testing for filth in four samples of apple juice from Argentina during fiscal year 1984 showed no excessive levels of filth, rot, or mold. Domestic producers, congressional sources, and others continued to raise questions about imported apple juice and apple juice concentrate. These concerns led to FDA's special investigation to analyze all shipments of apple juice concentrate imported between March 6, 1985, and May 8, 1985.

SECTION 2

OBJECTIVES, SCOPE, AND METHODOLOGY

In a letter from Representative Frank Horton, dated June 3, 1985, and subsequent discussions with his office, we were asked to review FDA's fiscal year 1985 special investigation on imported apple juice concentrate. On June 18, 1986, we agreed to provide information we obtained describing FDA's testing methodology and the results of its special investigation. In addition, we also agreed to provide data on the volume of U.S. imports of apple juice concentrate.

To obtain information on the special investigation and its testing methodology, we interviewed FDA officials at its Center for Food Safety and Applied Nutrition in Washington, D.C. We interviewed FDA officials representing three offices: the Division of Chemical Technology, the Division of Regulatory Guidance, and the Division of Program Operations. We obtained and reviewed pertinent files in order to analyze its special investigation. We also reviewed FDA's policy and procedures manuals.

To obtain information on tolerances, we interviewed EPA officials in four divisions in its Office of Pesticide Programs: the Hazard Evaluation Division, the Program Management and Support Division, the Benefits and Use Division, and the Registration Division. We reviewed Environmental Protection Agency documents relative to pesticide tolerance levels for apples and apple juice.

Also, we interviewed officials at the Department of Agriculture's Foreign Agricultural Service and Agricultural Research Service to obtain information on the volume of data. We interviewed New York Farm Bureau officials. We also reviewed Department of Commerce, Bureau of Census' data and reviewed documents from the American Farm Bureau Federation.

We discussed the matters contained in this fact sheet with responsible FDA officials, and their comments are incorporated where appropriate.

SECTION 3

FDA's SPECIAL INVESTIGATION:

OBJECTIVES AND APPROACH

FDA began the special investigation on imported apple juice on March 6, 1985. The special investigation's objectives were to analyze samples of each shipment of apple juice concentrate imported from March 6, 1985, through May 8, 1985, to determine whether they contained illegal pesticide residues.

TESTING APPROACH

All FDA field districts were instructed to sample each shipment arriving in its district during this period. If laboratory workload became overwhelming due to a large volume of imports, a minimum of five samples a week could be taken. In addition, sampling from a specific country could be terminated if any district encountered 15 nonviolative samples from that country.

Each sample was to be analyzed for the organophosphorus and organochlorine pesticides that FDA would regularly test apples/apple juice for using its standard multiresidue test methods. In addition, each sample was to be tested for mercury and daminozide because of allegations that levels of these chemicals were present in imported apple juice concentrate. Two additional single residue tests were required on each sample to test for mercury and daminozide because they are not detected by FDA's standard multiresidue test methods.

As part of our work we were asked to determine why FDA directed its laboratories to test the imported apple juice concentrate in an "as consumed" basis (adding distilled water in amounts necessary to convert the concentrate to the single-strength juice form) rather than on an "as is" basis. FDA's Pesticide Analytical Manual states that analytical results for concentrated and dehydrated products should be reported on an "as is" basis. The manual further states that when significant residues are found in concentrates that must be reconstituted to the whole product basis before consumption, it is useful to calculate to the whole basis and record both results. Rather than conduct the analysis in the manner prescribed in the manual, FDA chose to convert the apple juice concentrate to the whole product basis (single-strength apple juice) and to test and report on it in this form. All samples were reconstituted with distilled water prior to analysis in order to equalize concentrates of varying solid, sugar, and moisture content.

We discussed this decision with FDA officials. They told us that since imported apple juice concentrate is highly concentrated (six-strength) it would be difficult and not practical to test it

in this concentrated form. Apple juice concentrate is not consumed "as is," but processed into single-strength juice for consumption. Tolerances are generally not set for residues on those foods in an intermediate stage, that is, concentrates. No separate tolerances are set on apple juice concentrates. These officials further stated that they tested imported apple juice concentrates in the same manner that they test domestic apple juice concentrates--in the form of single-strength juice. Regarding the manual statement on testing in both the "as is" and "as consumed" basis, FDA officials said that the manual provides general guidance for chemists, but exceptions to prescribed procedures are allowed when it is appropriate to do so. On the basis of these reasons, FDA officials feel that their testing methodology was appropriate.

SECTION 4

FDA's SPECIAL INVESTIGATION:

FINDINGS AND TESTING RESULTS

A total of 267 samples representing 18 countries were collected by 16 FDA districts and tested by FDA laboratories. Samples from Austria, the Federal Republic of Germany, the Netherlands, and Spain comprised about 75 percent of the sample origins. Table 4.1 shows the number of samples by country of origin.

Table 4.1: Apple Juice Concentrate Samples by Country of Origin

Country	Number of samples
Austria	70
Germany, Fed. Rep.	60
Netherlands	39
Spain	28
Argentina	10
France	10
Canada	8
Rep. of S. Africa	8
Chile	6
Hungary	6
Turkey	6
Mexico	4
Yugoslavia	4
Australia	2
Denmark	2
German Dem. Rep.	2
Israel	1
New Zealand	1
Total	267

Source: Summary prepared by FDA.

FDA's testing results indicate that most samples contained no detectable residues. When residues were found, the levels detected fell well below allowable levels. The residue findings and associated allowable tolerance levels are detailed in table 4.2.

Table 4.2: Residue Findings on Apple Juice Concentrate and Associated Tolerances (Results reported on reconstituted basis)

Compound	Number of findings	Residue range	Allowable tolerance levels
		---(parts per million)-----	
Acephate	8	0.02-0.22	2.0
BHC, alpha	3	T-0.02	1.0
BHC, beta	2	0.01-0.02	1.0
Carbaryl	3	T-0.34	10.0
Daminozide	7	T	30.0
DDT, p,p'	2	T-0.01	0.1
TDE, p,p'	1	0.02	7.0
Dimethoate	26	T-0.10	2.0
Omethoate	13	T-0.23	2.0
Methamidophos	4	T-0.03	0.1[a]
Monocrotophos	2	T	0.2[a]
Tetrachlorvinphos	1	T	10.0

[a]FDA "regulatory analytical limits." Those limits are set for chemicals where a tolerance level does not exists. These levels are maximum pesticide residue limits intended to set triggers for FDA enforcement action.

Note: T=trace (<0.01 ppm for all chemicals except daminozide, <1.0ppm)

Source: Summary prepared by FDA.

The most frequently detected residue (dimethoate) was present in 26 of the 267 samples, or about 10 percent. The next most frequently occurring residue (omethoate) was present in about 5 percent of the total samples. Daminozide occurred in only seven samples (2.6 percent occurrence rate) at the trace level.

Mercury is a compound unavoidable in the air and the earth's crust. Residues do naturally occur at times in crops. Mercury levels were detected in nine samples (or about 3 percent of the total samples) at levels between trace and 0.06 parts per million. Neither allowable tolerance levels nor "regulatory analytical limits" are set for mercury. FDA officials said that the levels of mercury found are unavoidable and present no public health concern.

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